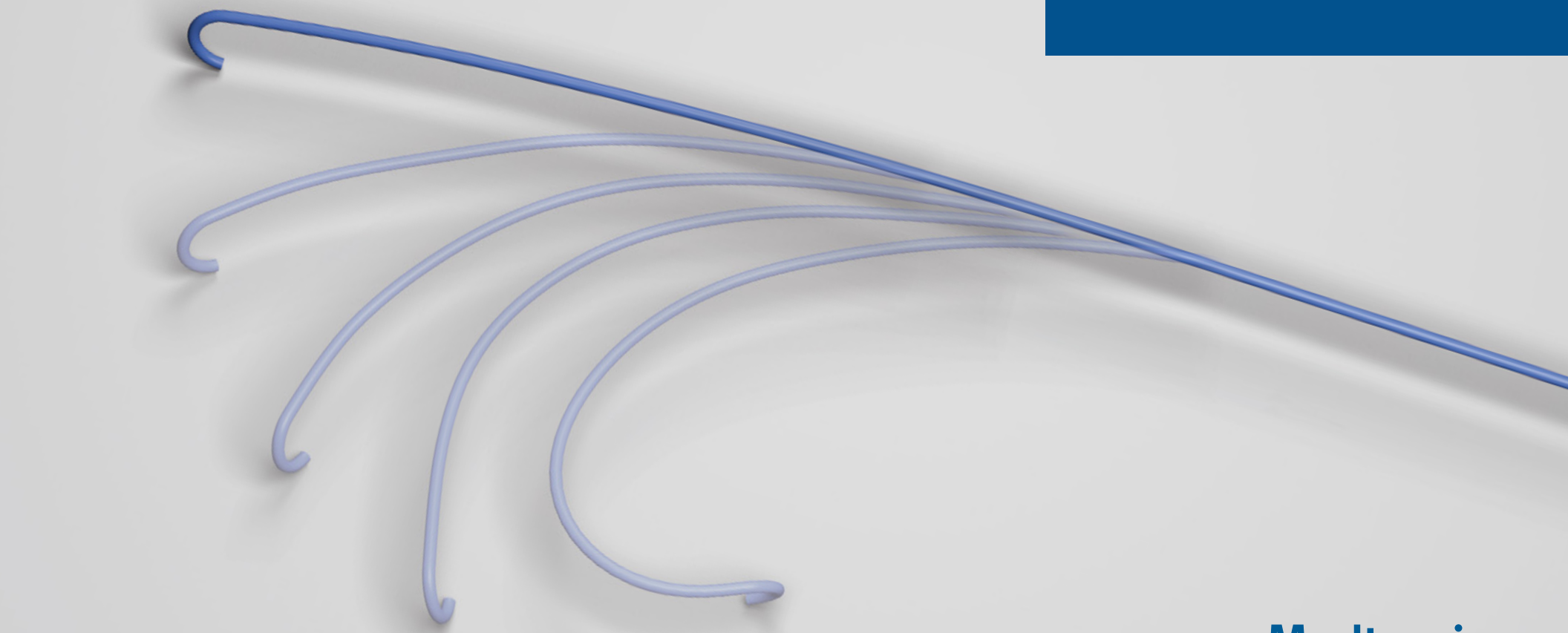
IMPROVED REACH. ENHANCED RANGE. HIS-BUNDLE PLACEMENT.

SelectSite™ C304-HIS Deflectable Catheter

Steerable, all-in-one system for lead delivery at or near the bundle of His.



Medtronic

FEATURES

1 IMPROVED REACH. ENHANCED RANGE.

- Adjustable curve designed to reach a large variety of patient anatomies* and accommodate challenging anatomical situations, including a large right atrium†
- Achieve various curve shapes during implant using only this steerable guide catheter
- Handle mechanism secures a desired shape, reducing the need to physically hold the curve in place during the procedure

2 STABLE AND SUPPORTIVE

- Rigid proximal portion provides mechanical support and stability for lead delivery and fixation; while the softer distal end minimizes tissue injury
- Catheter deflection is designed to push tip toward the targeted tissue and maintain stability on the septum
- Catheter provides a stable workspace to pass guidewires and leads in the cardiac venous anatomy
- Dual-braided lumen provides stability**

*Using Modeling Study of 20 different patient anatomies, selected to include patients with atria ranging from 38-197 mL RA volumes.
†Across tested anatomies, the C304-HIS improved fixation success rate in larger RAs with volumes between 110 mL and 139 mL (vs. C315).

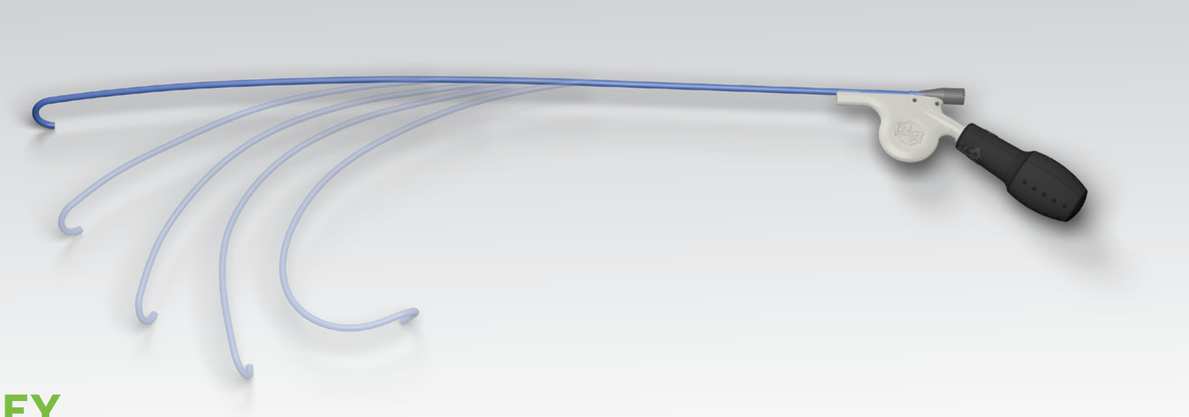
3 INCREASED IMPLANT SUCCESS

- The C304-HIS catheter design allows the tip to achieve an angle closer to perpendicular in the region of the His-bundle for a higher fixation rate vs. C315HIS catheter*†
- C304-HIS catheter may be used in conjunction with the Medtronic Model 3830 pacing lead
- The catheter body is radiopaque for visibility on fluoroscopy and has improved visualization of the catheter (vs. C304-L69) with an additional marker at the distal end

4 MANEUVERABILITY

- Handle mechanism enables tip deflection by transmitting fine movements to the catheter shaft, allowing placement at the bundle of His
- Designed for improved manipulation†† — deflect for gross movement, torque for minor movement
- Braided, kink-resistant catheter design with multiple transition zones allows for various stiffness characteristics, providing flexibility to navigate curvatures of venous anatomy

**Within the wall thickness of the device lumen is a second braided lumen for the pull wire.
††In comparison to C315HIS catheter.



KEY SPECIFICATIONS

This new tool complements the Medtronic portfolio of delivery catheters.

Feature	C304-HIS[1]	C315HIS[2]	C304-L69[3]
Primary Curve Shape	Deflectable + preshaped	Preshaped	Deflectable
Secondary Curve: Out-of-plane, “His” Shape Curve	Yes, preshaped	Yes, preshaped	None
Introducer	9 Fr	7 Fr	9 Fr
Usable Length	43 cm	43 cm	40 cm
Inner Diameter	5.7 Fr	5.4 Fr	5.7 Fr
Outer Diameter	8.4 Fr	7.0 Fr	8.4 Fr
Integrated Valve	No	Yes	No
Manipulation	Articulation handle	N/A	Articulation handle
Hydrophilic Coating	No	Yes	No
Shelf Life	2 years	2 years	2 years
Marker Band Material	2 gold marker bands	Tungsten Carbide	1 gold marker band
ETO Sterilization	Yes	Yes	Yes

Note: For His-bundle implantation, the C304-HIS catheter is used with the 3830-69 cm pacing lead.

References

[1] Medtronic SelectSite™ C304-HIS Deflectable Catheter System. Technical Manual, 2018.
[2] Medtronic C315H20, C315H40, C315HIS, C315J, C315S4, C315S5, C315S10 Delivery Catheter. Instructions for Use, 2016.
[3] Medtronic SelectSite™ C304-S59, C304-L69, C304-XL74. Instructions for Use. 2010.

Brief Statement
SelectSite™ C304-HIS Deflectable Catheter System

Indications

The device is indicated to provide a pathway through which diagnostic and therapeutic transvenous devices are introduced within the chambers and coronary vasculature of the heart and for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus.

Contraindications

Use of the device is contraindicated for patients with obstructed or inadequate vasculature and for right ventricular use in patients with tricuspid valvular disease or a mechanical tricuspid heart valve.

Warnings and Precautions

- The device is for single use only and is not intended to be resterilized.
- Use the deflectable catheter only with compatible transvenous devices. No test data is available to demonstrate compatibility of the deflectable catheter with any device not manufactured by Medtronic. For the C304-HIS Catheters, no test data is available to demonstrate compatibility of the transvenous devices with an outer diameter larger than 1.5 mm (4.6 Fr), with the exception of the 1.85 mm (5.6 Fr) dilator included with the device package. Consequences of using the deflectable catheter with incompatible devices may include the inability to deliver the transvenous device or damage to the transvenous device during delivery.
- Thrombogenicity evaluations were conducted using a heparinized model. If your patient cannot be adequately anticoagulated, it is unknown whether thrombus formation may occur with this product.
- Handle the deflectable catheter with care at all times. Do not kink, stretch, or severely bend the deflectable catheter. Do not use surgical instruments to grasp the deflectable catheter. Avoid contact with liquids other than isopropyl alcohol, blood, saline, or contrast solution.
- Use the valve to impede the backflow of venous blood during the implant procedure. Ensure that the flush port stopcock is closed before attaching the valve to the deflectable catheter hub.
- Keep external defibrillation equipment nearby for immediate use during acute lead system testing, the implant procedure, or whenever arrhythmias are possible or intentionally induced during post-implant testing.

Potential Complications

The following are known potential complications related to the use of the deflectable catheter system: air embolism, allergic reaction to contrast media, arteriovenous fistula formation, bleeding at the insertion site, brachial plexus injury, cardiac tamponade, dislodgement, dissection, endocarditis, heart block, hematoma formation, hemothorax, infection, irregular heartbeat, mediastinal widening, perforation, pneumothorax, subclavian artery puncture, thrombophlebitis, thrombosis, valve damage, vascular occlusion, and vessel damage.

See the device instructions for use for detailed information regarding the procedural instructions, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

medtronic.com

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